

# Exhibit 12

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CAMDEN VICINAGE**

IN RE: VALSARTAN, LOSARTAN, AND  
IRBESARTAN PRODUCTS LIABILITY  
LITIGATION

This Document Relates To:

*All Actions*

Hon. Robert. B. Kugler

Civ. No. 19-2875 (RBK/JS)

**PLAINTIFFS' SECOND AMENDED NOTICE OF VIDEOTAPED DEPOSITION  
TO MYLAN LABORATORIES, LTD., MYLAN N.V., AND  
MYLAN PHARMACEUTICALS, INC. PURSUANT TO FED. R. CIV. P. 30(b)(6)**

TO: Clem Trischler, Esq.  
Pietragallo Gordon Alfano Bosick & Raspanti LLP  
One Oxford Centre  
38th Floor  
Pittsburgh, PA 15219

*Counsel for Defendants Mylan Laboratories, Ltd., Mylan N.V., and Mylan  
Pharmaceuticals, Inc.*

PLEASE TAKE NOTICE that, pursuant to Fed. R. Civ. P. 30(b)(6), Plaintiffs will take the deposition upon oral examination of one or more designated corporate representatives with regard to the topics set forth on Exhibit A attached hereto. The deposition(s) will commence on a date to be determined, at 9:00 a.m., at a location to be determined, and continue from day to day as needed.

The deposition(s) will be taken upon oral examination before an officer authorized to administer oaths and will continue from day to day, until completed. Testimony given during the deposition will be recorded by sound video recording and stenographic means.

DATED this \_ day of November, 2020.

**MAZIE SLATER KATZ & FREEMAN, LLC**

By: /s/ Adam M. Slater

Adam M. Slater

103 Eisenhower Parkway, Suite 207

Roseland, New Jersey 07068

Telephone: 973-228-9898

***Attorneys for Plaintiffs***

**CERTIFICATE OF SERVICE**

I, Adam M. Slater, hereby certify that on November, 2020, I caused true and correct copies of the foregoing to be transmitted via ECF to all counsel having registered an appearance on ECF, with courtesy copies served on counsel for Mylan Laboratories, Ltd., Mylan N.V., and Mylan Pharmaceuticals, Inc., and Defendants' liaison counsel, via email.

DATED this \_\_ day of November, 2020.

**MAZIE SLATER KATZ & FREEMAN, LLC**

By: /s/ Adam M. Slater

Adam M. Slater  
103 Eisenhower Parkway, Suite 207  
Roseland, New Jersey 07068  
Telephone: 973-228-9898

***Attorneys for Plaintiffs***

**EXHIBIT A**

All topics reference information and documents known to, and/or in the possession, custody, or control of Mylan, in the ordinary course of its business.

All references to Mylan refer to all entities under the control of Mylan Laboratories, Ltd., Mylan N.V., and/or Mylan Pharmaceuticals, Inc. involved in the manufacture of valsartan API and/or finished dose sold in the United States.

All references to the “API,” Mylan’s API, or Mylan’s valsartan API are defined to include the valsartan API manufactured, sold, or distributed by Mylan

All references to “finished dose,” Mylan’s finished dose, or Mylan’s valsartan finished dose are defined to include the valsartan finished dose manufactured, sold, or distributed by Mylan.

In accordance with the Court’s Macro Discovery Order (ECF Doc No. 303), the terms “communications with any regulatory authority,” “disclosures to regulatory authorities,” and “filings with regulatory authorities” are limited to communications with the United States Food and Drug Administration, except insofar as the communications relate to regulatory inspection reports, warning letters, 483-like documents, responses to those documents, root cause analyses, and actual or potential nitrosamine contamination prior to July 2018, that were sent to or received from any foreign regulatory body during the designated relevant time period.

All references to testing are defined as testing capable of identifying the presence of nitrosamine contamination (i.e. NDMA, NDEA, NMBA), and/or detecting other carcinogens, general toxic impurities (including genotoxic impurities), and residual solvents, in connection with the manufacture and contents of Mylan’s valsartan API or finished dose, and include but are not limited to the following:

- Gas Chromatography (GC)
- Gas Chromatography- Flame Ionization Detector (GC-FID)
- Gas Chromatography- Mass Spectrometry (GC-MS)
- Gas Chromatography- tandem Mass Spectrometry (GC-MS/MS)
- Gas Chromatography- Selective Ion Monitoring Mass Spectrometry (GC-SIM MS)
- Gas Chromatography- High Resolution Mass Spectrometry (GC-HRMS)
- Gas Chromatography- Atomic Emission Spectrometry (GC-AES)
- Gas Chromatography- Flame Photometric Detector (GC-FPD)
- Gas Chromatography- Nitrogen Phosphorus Detector (GC-NPD)
- Gas Chromatography- Thermal Conductivity Detector (GC-TCD)
- Gas Chromatography- Photoionization Detector (GC-PID)
- Gas Chromatography- Electrolytic Conductivity Detector (GC-ELCD)
- Headspace Gas Chromatography (HS-GS)
- Liquid Chromatography (LC)
- High Performance Liquid Chromatography (HPLC)

- Liquid Chromatography-Mass Spectrometry (LC-MS)
- Liquid Chromatography-tandem Mass Spectrometry (LC-MS/MS)
- Liquid Chromatography- Selective Ion Monitoring Mass Spectrometry (LC-SIM MS)
- Liquid Chromatography- High Resolution Mass Spectrometry (LC-HRMS)
- Atomic Absorption Spectroscopy (AAS)
- Atomic Emission Spectrometry (AES)

### Testing

1. The cause of the contamination of Mylan's valsartan API with nitrosamines, including, but not limited to, NDMA and NDEA.
2. The root cause investigation for the nitrosamine impurities, including NDMA and NDEA in the Mylan API.
3. Any assessment or root cause analysis conducted by Lantech Pharmaceuticals with regard to NDMA and NDEA contamination in recycled or recovered solvents.
4. The testing performed by Mylan or its agents, to evaluate the purity and contents of Mylan's API, (regardless of intended sale location) manufactured in any facility that manufactured Mylan's valsartan API for sale in the United States.
5. The testing performed by any entity or person other than Mylan or its agents but known to Mylan, to evaluate the purity and contents of Mylan's valsartan API, (regardless of intended sale location) manufactured in any facility that manufactured Mylan's valsartan API for sale in the United States.
6. The testing performed by Mylan or its agents, to evaluate the purity and contents of Mylan's finished dose (regardless of intended sale location) manufactured in any facility that manufactured Mylan's valsartan finished dose for sale in the United States.
7. The testing performed by Mylan or its agents to evaluate the purity and contents of recovered or recycled solvents provided by Lantech Pharmaceuticals.
8. The testing performed by any entity or person other than Mylan or its agents but known to Mylan, to evaluate the purity and contents of Mylan's finished dose (regardless of intended sale location) manufactured in any facility that manufactured Mylan's valsartan finished dose for sale in the United States.
9. The chromatogram and mass spectrometry results for all testing by Mylan or its agents of Mylan's valsartan API (regardless of intended sale location) manufactured in any facility that manufactured Mylan's valsartan API for sale in the United States.
10. The chromatogram and mass spectrometry results for all testing by any entity or person other than Mylan or its agents but known to Mylan, of Mylan's valsartan API (regardless of intended sale location) manufactured in any facility that manufactured Mylan's valsartan API for sale in the United States.

11. The chromatogram and mass spectrometry or other results for all testing by Mylan or its agents of Mylan's finished dose (regardless of intended sale location) manufactured in any facility that manufactured Mylan's valsartan finished dose for sale in the United States.
12. The chromatogram and mass spectrometry or other results for all testing by any entity or person other than Mylan or its agents but known to Mylan, of Mylan's finished dose (regardless of intended sale location) manufactured in any facility that manufactured Mylan's valsartan finished dose for sale in the United States.
13. Mylan's evaluation of the potential risks to the purity or contents of Mylan's API posed or caused by solvents used during the manufacturing process (regardless of intended sale location) in any facility that manufactured Mylan's valsartan API for sale in the United States.
- ~~13.~~14. Mylan's evaluation of the potential risks to the purity or contents of Mylan's finished dose posed or caused by solvents used during the manufacturing process (regardless of intended sale location) in any facility that manufactured Mylan's valsartan finished dose for sale in the United States.
- ~~14.~~15. The chromatogram and mass spectrometry results for all testing by Mylan or its agents of the solvents utilized in the manufacture of Mylan's valsartan API (regardless of intended sale location) in any facility that manufactured Mylan's valsartan API for sale in the United States.
16. The chromatogram and mass spectrometry results for all testing by any entity or person other than Mylan or its agents but known to Mylan, of the solvents utilized in the manufacture of Mylan's API (regardless of intended sale location) in any facility that manufactured Mylan's valsartan API for sale in the United States.
17. The chromatogram and mass spectrometry results for all testing by Mylan or its agents of the solvents utilized in the manufacture of Mylan's valsartan finished dose (regardless of intended sale location) in any facility that manufactured Mylan's valsartan finished dose for sale in the United States.
- ~~15.~~18. The chromatogram and mass spectrometry results for all testing by any entity or person other than Mylan or its agents but known to Mylan, of the solvents utilized in the manufacture of Mylan's finished dose (regardless of intended sale location) in any facility that manufactured Mylan's valsartan finished dose for sale in the United States.
- ~~16.~~19. The extent of the actual and potential nitrosamine contamination of Mylan's valsartan API and finished dose sold in the United States, both in terms of the concentration per pill, and across all of the lots/batches.

**Quality Assurance and Quality Control Activities**

20. Mylan's Standard Operating Procedures ("SOPs"), policies or procedures intended to prevent, detect, or act in response to any impurity or contamination, for example

carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in connection with the manufacture and contents of Mylan's valsartan API (regardless of intended sale location) in any facility that manufactured Mylan's valsartan API for sale in the United States. (The parties to meet and confer to identify the relevant SOP's, policies, or procedures.)

~~17.~~21. Mylan's Standard Operating Procedures ("SOPs"), policies or procedures intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in connection with the manufacture and contents of Mylan's valsartan finished dose (regardless of intended sale location) in any facility that manufactured Mylan's valsartan finished dose for sale in the United States. (The parties to meet and confer to identify the relevant SOP's, policies, or procedures.)

22. Mylan's application of cGMPs in connection with the manufacture of Mylan's valsartan API (regardless of intended sale location) in any facility that manufactured Mylan's valsartan API for sale in the United States. (The parties to meet and confer to identify the relevant cGMP's.)

~~18.~~23. Mylan's application of cGMPs in connection with the manufacture of Mylan's valsartan finished dose (regardless of intended sale location) in any facility that manufactured Mylan's valsartan finished dose for sale in the United States. (The parties to meet and confer to identify the relevant cGMP's.)

~~19.~~24. Mylan's SOPs/policies/procedures for procurement of recovered or recycled solvents, and selection of vendors to provide such services.

### **Process Development**

~~20.~~25. The development of each Drug Master File for Mylan's valsartan API sold in the United States, including any risk assessments conducted on starting materials, or solvents.

~~21.~~26. The use of solvents, and the Tetrazole ring formation step, in the manufacturing process for Mylan's valsartan API, including: (1) the reasons for each, and any modifications, (2) the testing and evaluation in connection with each, including any modification, and (3) the relationship between each, including any modifications, and the nitrosamine contamination of Mylan's valsartan API, (regardless of intended sale location) in any facility that manufactured Mylan's valsartan API for sale in the United States.

~~22.~~27. Any evaluation conducted by or on behalf of Mylan with regard to health or safety issues arising from the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for Mylan's valsartan API (regardless of intended sale location) in any facility that manufactured Mylan's valsartan API for sale in the United States.

~~23.~~28. Mylan's evaluation and knowledge of the risk of the creation of nitrosamines including NDMA and NDEA as a result of the manufacturing process for Mylan's valsartan API.



~~24.~~29. Mylan's evaluation and knowledge of the risk of using recovered or recycled solvents in the Tetrazole ring formation step, in the manufacturing process for Mylan's valsartan API.

30. Mylan's evaluation and knowledge of the health risks of nitrosamines including NDMA and NDEA, including but not limited to as a contaminant of Mylan's valsartan API.

~~25.~~31. Mylan's evaluation and knowledge of the health risks of nitrosamines including NDMA and NDEA, including but not limited to as a contaminant of Mylan's valsartan finished dose.

**Communications with Regulatory Agencies**

~~26.~~32. The communications with any regulatory authority, including but not limited to the FDA, with regard to the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for Mylan's valsartan API.

33. Mylan's communications with regulatory authorities, including the FDA, with regard to the actual or potential contamination of Mylan's valsartan API with nitrosamines including NDMA and NDEA.

~~27.~~34. Mylan's communications with regulatory authorities, including the FDA, with regard to the actual or potential contamination of Mylan's valsartan finished dose with nitrosamines including NDMA and NDEA.

~~28.~~35. Mylan's filings with regulatory authorities, including the FDA, regarding manufacturing process changes for Mylan's Valsartan API Drug Master Filings.

**Mylan's Communications with Finished Dose Customers and Downstream Customers**

36. Mylan's oral and written communications with its valsartan API Customers (including vertically integrated facilities) or other downstream entities (i.e. wholesalers, retailers, consumers, TPP's) regarding quality, purity, or contamination issues related to the Mylan API.

~~29.~~37. Mylan's oral and written communications with its valsartan finished dose Customers (including vertically integrated facilities) or other downstream entities (i.e. wholesalers, retailers, consumers, TPP's) regarding quality, purity, or contamination issues related to the Mylan's finished dose.

38. Mylan's oral and written statements to finished dose manufacturers, wholesalers, retailers, and consumers with regard to the contents and purity of Mylan's valsartan API.

~~30.~~39. Mylan's oral and written statements to finished dose manufacturers, wholesalers, retailers, and consumers with regard to the contents and purity of Mylan's valsartan finished dose.

40. Mylan's product recall for valsartan API, including who Mylan communicated with, how, about what, and the retention of recalled or sequestered Mylan valsartan API, including as a component of finished dose.

31.41. Mylan's product recall for valsartan API, including who Mylan communicated with, how, about what, and the retention of recalled or sequestered Mylan valsartan finished dose.

32.42. All credits, indemnification, refunds, and/or penalties paid or provided by or to Mylan in connection with the nitrosamine contamination of Mylan's valsartan API and finished dose.

**Compliance with cGMPs**

33.43. Mylan's compliance or non-compliance with cGMPs as it relates to the manufacture, quality assurance, quality control, and sale of Mylan's API and finished dose (regardless of intended sale location) in any facility that manufactured Mylan's valsartan API or finished dose for sale in the United States.

34.44. The policies, practices, procedures and trainings for monitoring compliance with cGMPs (regardless of intended sale location) in any facility that manufactured Mylan's valsartan API or finished dose for sale in the United States.

35.45. The policies, practices, procedures and trainings for monitoring material providers (such as Lantech Pharmaceuticals) and their compliance with cGMPs.

**Product Tracing**

46. Tracing of batches and lots of Mylan's valsartan API sold downstream and ultimately intended for use by consumers in the United States.

36.47. Tracing of batches and lots of Mylan's valsartan finished dose sold downstream and ultimately intended for use by consumers in the United States.

37.48. The pricing of Mylan's valsartan API that was ultimately sold in the United States.

38.49. The pricing of Mylan's valsartan finished dose that was ultimately sold in the United States.

39.50. The gross and net profits to Mylan from the sale of Mylan's valsartan API in the United States.

40.51. The gross and net profits to Mylan from the sale of Mylan's valsartan finished dose in the United States.

41.52. The quantity/units of Mylan's valsartan finished dose sold in the United States.

42.53. Mylan's valsartan API sales and pricing data produced by you in this litigation (sample documents to be provided ahead of deposition during meet and confer process).

~~43.54.~~ Mylan's valsartan finished dose sales and pricing data produced by you in this litigation (sample documents to be provided ahead of deposition during meet and confer process).